

IFW

DOCKET NO.: TRUC-0016

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Thomas S. Scanlan, Matthew E. Hart,  
David K. Grandy, James R. Bunzow,  
Mononori Miyakawa, Edwin Saavedra Tan,  
and Katherine L. Suchland

Confirmation No.: 8599

Application No.: 10/825,881

Group Art Unit: 1621

Filing Date: April 16, 2004

Examiner: Not Yet Assigned

For: **THYRONAMINE DERIVATIVES AND ANALOGS AND METHODS OF USE  
THEREOF**

DATE OF DEPOSIT: August 5, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING  
DEPOSITED WITH THE UNITED STATES POSTAL  
SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID,  
ON THE DATE INDICATED ABOVE AND IS  
ADDRESSED TO THE UNITED STATES PATENT AND  
TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA,  
VA 22313-1450

TYPED NAME: Phillip A. Singer  
REGISTRATION NO.: 40,176

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

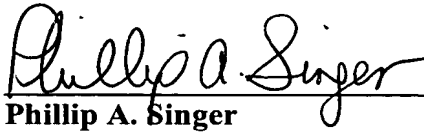
- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.
- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:
- ☐ Certification in Accordance with § 1.97(e) is attached; or
- ☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.
- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with § 1.97(e) is attached;
- or
- ☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.
- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☒ Copies of references **43-52 and 57-68** listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).
- ☒ In view of the voluminous nature of references **34-42**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☒ Copies of references **1-21** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **10/418,399**, filed **April 18, 2003**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no newly cited references which are not in the English language.

Date: **August 5, 2004**

  
**Phillip A. Singer**  
Registration No. 40,176

**WOODCOCK WASHBURN LLP**  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		<b>Docket No.</b> <b>TRUC-0016</b>	<b>Application No.</b> <b>10/825,881</b>
		<b>Applicant</b> <b>Thomas S. Scanlan, Matthew E. Hart,</b> <b>David K. Grandy, James R. Bunzow,</b> <b>Mononori Miyakawa, Edwin Saavedra Tan,</b> <b>and Katherine L. Suchland</b>	
		<b>Filing Date</b> <b>April 16, 2004</b>	<b>Group</b> <b>1621</b>
		<b>Confirmation No.</b> <b>8599</b>	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	1	Biondi B. et al., "Effects of Subclinical Thyroid Dysfunction on the Heart," <i>Ann Intern Med.</i> , <b>2002</b> , 137, 904-914	
	2	Boissier, J.R. et al., "Differential Inotropic-Chronotropic Action of Thyronamine," <i>Eur. J. Pharmacol.</i> , <b>1973</b> , 22, 141-149	
	3	Borowsky, B. et al., "Trace amines: Identification of a family of mammalian G protein-coupled receptors," <i>Proc. Natl. Acad. Sci.</i> , <b>2001</b> , 98(16), 8966-8971	
	4	Bunzow, J.R. et al., "Amphetamine, 3,4-Methylenedioxymethamphetamine, Lysergic Acid Diethylamide, and Metabolites of the Catecholamine Neurotransmitters are Agonists of a Rat Trace Amine Receptor," <i>Mol. Pharmacol.</i> , <b>2001</b> , 60, 1181-1188	
	5	Buu-Hoi, N.P., "Some Biological Effects of Thyronamine," <i>Med. Pharmacol. Exp.</i> , <b>1966</b> , 15, 17-23	
	6	Buu-Hoi, N.P. et al., "Thyronamine, a New Substance with Long-acting Positive Inotropic Effect," <i>Pharmacology</i> , <b>1969</b> , 2, 281-287	
	7	Cody, V. et al., "Molecular Structure and Biochemical Activity of 3,5,3'-Triiodothyronamine," <i>Endocrine Research</i> , <b>1984</b> , 10(2), 91-99	
	8	Cote, P. et al., "Thyronamine, a new inotropic agent: its cardiovascular effects and mechanism of action," <i>Cardiovascular Res.</i> , <b>1974</b> , 8, 721-730	
	9	Dratman, M.B., "On the Mechanism if Action of Thyroxine, an Amino Acid Analog of Tyrosine," <i>J. Theor. Biol.</i> , <b>1974</b> , 46, 255-270	
	10	Falkenstein, E. et al., "Multiple Actions of Steroid Hormones-A Focus on Rapid, Nongenomic Effects," <i>Pharmacol. Rev.</i> , <b>2000</b> , 52(4), 513-555	
	11	Hamilton, M.A. et al., "Safety and Hemodynamic Effects of Intravenous Triiodothyronine in Advanced Congestive Heart Failure," <i>Am. J. Cardiol.</i> <b>1998</b> , 81, 443-447	
	12	Han, S-Y. et al., "Synthesis of side chain-modified idothyronines," <i>Int. J. Peptide Protein Res.</i> , <b>1987</b> , 30, 652-661	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	<b>Docket No.</b> TRUC-0016	<b>Application No.</b> 10/825,881
	<b>Applicant</b> Thomas S. Scanlan, Matthew E. Hart, David K. Grandy, James R. Bunzow, Mononori Miyakawa, Edwin Saavedra Tan, and Katherine L. Suchland	
	<b>Filing Date</b> April 16, 2004	<b>Group</b> 1621
	<b>Confirmation No.</b> 8599	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
	<b>13</b> Meyer, T., "Triiodothyronamine-A Beta-adrenergic Metabolite of Triiodothyronine?" <i>Horm. Metabol. Res.</i> , <b>1983</b> , 15, 602-606	
	<b>14</b> Petit, L. et al., "A Synthesis of Thyronamine and Its Lower Homolog," <i>J. Org. Chem.</i> , <b>1961</b> , 26, 3832-3834	
	<b>15</b> Rozanov, C.B. et al., "Immunohistochemical Mapping of Brain Triiodothyronine Reveals Prominent Localization in Central Noradrenergic Systems," <i>Neuroscience</i> , <b>1996</b> , 74(3), 897-915	
	<b>16</b> Stöhr, R., "Synthese des Thyronamins," <i>Hoppe-Seyler Z. physiol. Chem.</i> , <b>1931</b> , 201, 142	
	<b>17</b> Sun, Z.-Q. et al., "Effects of thyroid hormone on action potential and repolarizing currents in rat ventricular myocytes," <i>Am. J. Physiol. Endocrinol. Metab.</i> , <b>2000</b> , 278, E302-E307	
	<b>18</b> Thibault, O., "Recherhes sur la nature de la «thyroxine active» . Renforcement immediate par la thyroxamine des effets de l'adrénaline sur divers muscles lisses," <i>C. R. Soc. Chim. Biol.</i> , <b>1951</b> , 797-800	
	<b>19</b> Tomita, K. et al., "Synthesis and Biological Activity of Some Triiodinated Analogues of Thyroxine," <i>J. Biol. Chem.</i> , <b>1956</b> , 219, 595-604	
	<b>20</b> Walker, J.D. et al., "The novel effects of 3,5,3'-triiodo-L-thyronine on myocyte contractile function and $\beta$ -adrenergic responsivness in dilated cardiomyopathy," <i>J. Thorac. Cardiovasc. Surg.</i> , <b>1994</b> , 108, 672-679	
	<b>21</b> Yen, P.M., "Physiological and Molecular Basis of Thyroid Hormone Action," <i>Physiol. Rev.</i> , <b>2001</b> , 81(3), 1097-1142	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	<b>Docket No.</b> TRUC-0016	<b>Application No.</b> 10/825,881
	<b>Applicant</b> Thomas S. Scanlan, Matthew E. Hart, David K. Grandy, James R. Bunzow, Mononori Miyakawa, Edwin Saavedra Tan, and Katherine L. Suchland	
	<b>Filing Date</b> April 16, 2004	<b>Group</b> 1621
	<b>Confirmation No.</b> 8599	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
	22	Akerstrom, B. et al., "Protein G: A Powerful Tool for Binding and Detection of Monoclonal and Polyclonal Antibodies," <i>J. Immunol.</i> , <b>1985</b> , 135(4), 2589-2592
	23	Fingl, E. et al., "General Principles," <i>The Pharmacological Basis of Therapeutics</i> , <b>1975</b> , Goodman, L.S. et al. (eds.), Chapter 1, Fifth Edition, 1-46
	24	Huse, W.D. et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda," <i>Science</i> , <b>1989</b> , 246, 1275-1281
	25	Köhler, G. et al., "Derivation of Specific Antibody-Producing Tissue Culture and Tumor Lines by Cell Fusion," <i>Eur. J. Immunol.</i> , <b>1976</b> , 6, 511-519
	26	Köhler, G. et al., "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity," <i>Nature</i> , <b>1975</b> , 256, 495-497
	27	Kronval, G., "A Surface Component in Group A, C, and G Streptococci with Non-Immune Reactivity for Immunoglobulin G," <i>J. Immunol.</i> , <b>1973</b> , 111(5), 1401-1406
	28	Monroe, D., "Liposome Immunoassay: A New Ultrasensitive Analytical Method," <i>Amer. Clin. Prod. Rev.</i> , <b>1986</b> , 5, 34-41
	29	Nillne, E.A. et al., "Deficiencies in Pro-thyrotropin-releasing Hormone Processing and Abnormalities in Thermoregulation in <i>Cpe<sup>fa/fa</sup></i> Mice," <i>J. Biol. Chem.</i> , <b>2002</b> , 277(50), 48587-48595
	30	Östberg, L. et al., "Human x (Mouse x Human) Hybridomas Stably Producing Human Antibodies," <i>Hybridoma</i> , <b>1983</b> , 2(4), 361-367
	31	Queen, C. et al., "A Humanized Antibody that Binds to the Interleukin 2 Receptor," <i>Proc. Natl. Acad. Sci. USA</i> , <b>1989</b> , 86, 10029-10033
	32	Ribeiro, M.O. et al., "Thyroid hormone-sympathetic interaction and adaptive thermogenesis are thyroid hormone receptor isoform-specific," <i>J. Clin. Invest.</i> , <b>2001</b> , 108(1), 97-105
	33	Ward, E.S. et al., "Binding Activities of a Repertoire of Single Immunoglobulin Variable Domains Secreted from <i>Escherichia coli</i> ," <i>Nature</i> , <b>1989</b> , 341, 544-546
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	<b>Docket No.</b> <b>TRUC-0016</b>	<b>Application No.</b> <b>10/825,881</b>
	<b>Applicant</b> <b>Thomas S. Scanlan, Matthew E. Hart,</b> <b>David K. Grandy, James R. Bunzow,</b> <b>Mononori Miyakawa, Edwin Saavedra Tan,</b> <b>and Katherine L. Suchland</b>	
	<b>Filing Date</b> <b>April 16, 2004</b>	<b>Group</b> <b>1621</b>
	<b>Confirmation No.</b> <b>8599</b>	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

*	<b>34</b>	Asai (ed.), <i>Methods in Cell Biology: Antibodies in Cell Biology</i> , Asai, Vol. 37, 1993
*	<b>35</b>	Coligan, <i>Current Protocols in Immunology</i> , 1991
*	<b>36</b>	Crowther, John R., <i>ELISA Theory and Practice</i> , Humana Press: New Jersey, 1995
*	<b>37</b>	Maggio (ed.), <i>Enzyme Immunoassay</i> , 1980
*	<b>38</b>	Goding, <i>Monoclonal Antibodies: Principles and Practice</i> , 2d ed., 1986
*	<b>39</b>	Greene and Wuts, <i>Protective Groups in Organic Synthesis</i> , 2d ed., John Wiley & Sons, New York, 1991
*	<b>40</b>	Harlow and Lane, <i>Antibodies: A Laboratory Manual</i> , Cold Spring Harbor Laboratory, 1988
*	<b>41</b>	<i>Remington's Pharmaceutical Sciences</i> , Mack Publishing Co., Easton, Pennsylvania, 18 <sup>th</sup> ed., 1990
*	<b>42</b>	Stites et al. (eds.), <i>Basic and Clinical Immunology</i> , 7th ed., 1991

**EXAMINER****DATE CONSIDERED**

\*In view of the voluminous nature of references XX-XX, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	<b>Docket No.</b> TRUC-0016	<b>Application No.</b> 10/825,881
	<b>Applicant</b> Thomas S. Scanlan, Matthew E. Hart, David K. Grandy, James R. Bunzow, Mononori Miyakawa, Edwin Saavedra Tan, and Katherine L. Suchland	
	<b>Filing Date</b> April 16, 2004	<b>Group</b> 1621
	<b>Confirmation No.</b> 8599	

### U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	43	4,366,241	12/28/82	Tom et al.	435	7.91
	44	4,376,110	03/08/83	David et al.	435	5
	45	4,391,904	07/05/83	Litman et al.	435	7.91
	46	4,517,288	05/14/85	Giegel et al.	435	5
	47	4,634,664	01/06/87	Oestberg	435	70.21
	48	4,634,666	01/06/87	Engleman et al.	435	70.21
	49	4,837,168	06/06/89	de Jaeger et al.	436	533
	50	5,225,539	07/06/93	Winter	530	387.3
	51	5,530,101	06/25/96	Queen et al.	530	387.3
	52	5,565,332	10/15/96	Hoogenboom et al.	435	69.1

### FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	53	WO 90/07861	07/26/90	PCT		
	54	WO 91/17271	11/14/91	PCT		
	55	WO 92/01047	01/23/92	PCT		
	56	WO 92/22653	12/23/92	PCT		

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	<b>Docket No.</b> TRUC-0016	<b>Application No.</b> 10/825,881
	<b>Applicant</b> Thomas S. Scanlan, Matthew E. Hart, David K. Grandy, James R. Bunzow, Mononori Miyakawa, Edwin Saavedra Tan, and Katherine L. Suchland	
	<b>Filing Date</b> April 16, 2004	<b>Group</b> 1621
	<b>Confirmation No.</b> 8599	

### U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	57	5,585,089	12/17/96	Queen et al.	424	133.1
	58	5,693,761	12/02/97	Queen et al.	536	23.53
	59	5,693,762	12/02/97	Queen et al.	530	387.3
	60	5,733,743	03/31/98	Johnson et al.	435	69.1
	61	5,837,242	11/17/98	Holliger et al.	424	136.1
	62	5,858,657	01/12/99	Winter et al.	435	6
	63	5,871,907	02/16/99	Winter et al.	435	6
	64	5,877,218	03/02/99	Herzig et al.	514	617
	65	5,969,108	10/19/99	McCafferty et al.	530	387.3
	66	5,994,519	11/30/99	Osborn et al.	530	413
	67	6,172,197	01/19/01	McCafferty et al.	530	387.3
	68	6,180,336	01/30/01	Osborn et al.	435	5

### FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO

EXAMINER

DATE CONSIDERED